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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,987	10/01/2001	Andrew D. Murdin	032931-0253	7970

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,987

Applicant(s)

MURDIN ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 and 79-83 is/are pending in the application.
- 4a) Of the above claim(s) 20-24, 25-35, 37, 38 (c) and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 36, 38(a), (b) 79 and 80-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.


LYNETTE R. J. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Response to Amendment

Amendment

1. Applicant's amendment filed on 4/7/04 is acknowledged.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Status of claims

3. Claims 1-4, 7-16, 25, 38, 79 and 80 have been amended in the current amendment (4/7/04).

Claims 18-19 have been canceled.

New claims 81-83 have been entered.

Newly added claims 81-83 are drawn to nucleic acid and therefore, added to the elected invention.

Claim 25 depends from a non-elected claim 21 and therefore, is withdrawn from the elected invention.

Claims 1-19, 36, 38(a), (b), 79 and 80-83 are under prosecution as an elected invention, said election made on 12/4/02.

Claim Rejection - 35 U.S.C. 102 moot

4. In view of cancelation of claims 18 and 19, the rejection under 35 U.S.C. 102(b) as being clearly anticipated by Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 Product Catalog, page 66), Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60- 62) is moot.

35 U.S.C. 112 written description rejection maintained

5. The rejection of claims 1-19, 36, 38(a) (b), and 79-83 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained as set forth in the previous office action.

Applicant continues to traverse the rejection. However, Applicants' arguments have been fully considered but they are not deemed to be persuasive.

Applicant states that the limitation 75% identity has been deleted from the claims and now the claims recite only fragments of elected sequences and such fragments have been disclosed in the specification and therefore, the rejection should be withdrawn.

The examiner disagrees with the applicant because the specification does not disclose fragments as claimed. It is noted that the specification fails to provide support for an isolated nucleic acid molecule comprising (open language) a nucleic acid molecule which encodes a polypeptide selected from an immunogenic fragment comprising 50 or 12 consecutive amino acid from SEQ.ID.NO: 14. This isolated nucleic acid molecule is not limited to fragments of SEQ.ID.NO: 14 but reads on any nucleic acid molecule comprising a nucleic acid which encodes 50 or 12 consecutive amino acids from SEQ.ID.NO: 14. Similarly, an isolated nucleic acid molecule comprising at least 38 or 100 consecutive nucleic acids from SEQ.ID.NO: 1, is not restricted to an isolated polypeptide consisting of at least 38 or 100 consecutive nucleic acids from SEQ.ID.NO: 1. Applicant is claiming an isolated nucleic acid comprising a nucleic acid molecule, which encodes said fragment without specific and substantial function for the claimed fragments. Therefore, the rejection is proper and maintained.

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35 U.S.C. 112 scope rejection maintained

6. The rejection of claims 1-19, 36, 38 (a) (b), 79- 83 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule comprising the nucleic acid sequence as set forth in SEQ ID NO: 1, an isolated nucleic acid molecule comprising a nucleic acid molecule encoding the amino acid sequence as set forth in SEQ.ID.NO: 14, vector comprising said nucleic acid, host cell comprising said vector, and pharmaceutical composition comprising said nucleic acid, the specification does not reasonably provide enablement for an nucleic acid comprising a nucleic acid molecule encoding fragments of SEQ.ID.NO: 14 or a nucleic acid molecule comprising fragments of SEQ.ID.NO: 1 is maintained as set forth in the previous Office action.

Applicant's arguments filed on 6/27/03 have been fully considered but they are not deemed to be persuasive. First, Applicant states that the instant application is not concerned with the biological activity of the protein but rather the specification describes the claimed nucleic acid and polypeptides in terms of their utility as immunogenic compounds. Further, applicant argues that peptides 6-15 amino acids generate an immune response and antibodies to such peptides are commercially available.

First, the examiner would like to clarify the issue of "biological activity and utility" because in applicant's concept peptide biological activity and utility as immunogenic compounds are different. It is very well know in the art of immunology to make antibodies even to peptide having 5-8 amino acids. However, the antibodies produced by such peptide should be able to recognize the full-length protein and thus the peptide is immunogenic and has the ability to bind to an antibody (property/function). Thus, an immunogenic compound i.e., fragment has utility with a specific function. If the applicant

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is not concerned with the activity of such peptides, then the claims that recite fragments have no specific and substantial utility because the fragments have no function.

Secondly, Applicant asserts that the limitation 75% identity has been deleted from the claims and now the claims recite fragments and therefore, the rejection should be withdrawn.

The examiner disagrees with the applicant because the specification does not disclose an isolated nucleic acid molecule comprising a nucleic acid molecule which encodes a polypeptide selected from an immunogenic fragment comprising 50 or 12 consecutive amino acid from SEQ.ID.NO: 14 or e an isolated nucleic acid molecule comprising a nucleic acid molecule at least a 38 or 100 consecutive nucleic acids from SEQ.ID.NO: 1, vaccine vector comprising said fragments etc

Finally, the examiner would like to point to the applicant that fragments as claimed are not shorter than SEQ.ID.NO: 14 because applicant is claiming isolated nucleic acid molecule comprising (open language) a nucleic acid molecule which encodes a polypeptide selected from an immunogenic fragment comprising 50 or 12 consecutive amino acid from SEQ.ID.NO: 14 or at least a 38 or 100 consecutive nucleic acids from SEQ.ID.NO: 1 and thus claiming an isolated nucleic acid comprising unlimited and unknown nucleic acids without any function. Thus, the fragments as claimed are broader than the claimed SEQ.ID.NO: 14 or SEQ.ID.NO: 1. Please note applicant is not claiming an isolated nucleotide acid molecule consisting of 50 or 12 consecutive amino acid as set forth in SEQ.ID.NO: 14 or an isolated nucleotide acid molecule consisting of at least 38 or 100 consecutive nucleic acids as set forth in SEQ.ID.NO: 1.

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Claim Rejection - 35 USC 102 maintained

7. The rejection of claims 1, 2, 8, 16, 38 (a) (b) and 79-81 under 35 U.S.C. 102(e) as being clearly anticipated by Griffais U.S.Patent 6, 559, 294 is maintained as set forth in the previous office action.

Griffais U.S.Patent 6, 559, 294 discloses a nucleic acid sequence (SEQ.ID.NO: 1, see the sequence alignment) from *C. pneumoniae* which encodes a polypeptide SEQ.ID.NO: 14, immunogenic fragment comprising at least 50 consecutive amino acids, nucleic acid molecule comprising 38 consecutive nucleotides (see the sequence alignment) and is 98.3 % identical to SEQ ID NO: 14. Therefore, the prior art meets the limitations of claimed nucleic acid molecule. The prior art anticipated the claimed invention.

Please note that the examiner has clearly indicated that the examiner is unable to locate the application 09/198,452 (U.S.Patent 6, 559, 294) in the previous Office action and the examiner is using the filing date of this application 11/23/1998 as 102 (e) date. However, the application has been reviewed and found that the 102 (e) for the Griffais U.S.Patent 6, 559, 294 is 11/21/1997.

The Declaration provided by Andrew Murdin under 37 CFR 1.132 filed 4/07/04 is acknowledged. However, the Declaration is insufficient to overcome the rejection based upon 102(e) date because the Declaration does not provide that the applicant has possessed the claimed sequences prior to 11/21/1997 as required.

Remarks

8. No claims are allowed.

Conclusion

9. This application contains claims 20-24, 26-35, 36, 37, 38 (c) and 39 that are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time

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policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

11. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general

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nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.